REMARKS / ARGUMENTS

Status of the claims

Claims 1, 6-9 and 18-25 have been examined and are rejected on various grounds. These rejections are addressed in the appropriate sections below. Claims 21-23 have been withdrawn from further consideration as being drawn to a nonelected invention.

By virtue of this amendment, claims 1, 18 and 20 are amended, and claims 7, 8, and 9 are canceled. Upon entry of this amendment, claims 1, 6, 18-20 and 24 will be pending. Claim 1 has been amended to incorporate the description of claim 9. Claims 18 and 20 have been amended to recite the proper claim dependency upon the cancellation of base claim 9. The amendments to the claims have been made in an effort to place them in condition for allowance or in better form for appeal. The claim amendments are not to be construed as an agreement or acquiescence of the correctness of the rejection or of the Examiner's position. Applicants reserve the right to prosecute the cancelled subject matter at a later date. No new matter has been introduced by the above amendments.

Entry of these amendments and reexamination and reconsideration of the claims, as amended, are respectfully requested.

Rejections under 35 U.S.C §112, first paragraph

Claims 1, 6-8 and 19 have been rejected under 35 U.S.C §112, first paragraph on various grounds. The Examiner acknowledges that Applicants are in possession of a method of treating rheumatoid arthritis comprising administering to a mammal in need thereof effective amounts of an anti-CD11a antibody and a TNF-α receptor - IgG Fc fusion protein. However, the Examiner comments that the claims encompass a broad genus of TNF-α antagonists with unlimited number of possibilities with regard to the length of the TNF-α binding portion of the TNF receptor. In addition, it is remarked that the specification does not provide sufficient guidance as to which amino acids of TNF-α would have been altered such that the resultant molecule would retain the function to transduce cytotoxic and proliferative signals.

Applicants remark that for the purposes of the present methods of the invention, the TNF-α antagonists function to compete for binding to TNF-α, thus blocking the binding of the ligand to its native receptor on cells. The TNF-α antagonist serves as a blocker; it is not being relied upon to transduce cytotoxic and proliferative signals. Thus, it is not necessary for the specification to teach the parts of the receptor that would retain these functions. TNF receptors

are a well studied family of molecules; the regions of the receptor that bind the ligand are well established in the literature and need not be reproduced in the specification. Moreover, since the domain structure and sequence of the receptor are known, one of skill in the art would have been able to determine by routine methods such as by genetically engineering constructs to test each domain or by mutational analysis, which residues of the receptor are sufficient to construct the immunoadhesin or other fusion protein antagonists.

However, in the interest of expediting prosecution, claim 1 has been amended to incorporate the description of claim 9, and claim 9 is now canceled. Applicants believe the amendment to claim 1 overcomes this rejection. The withdrawal of this rejection is respectfully requested.

Rejections under 35 U.S.C §103

Claims 1, 6-9, 18-20 and 24-25 are rejected under 35 U.S.C. §103 (a) as allegedly unpatentable over U.S. Patent No. 6,037,454, in view of U.S. Patent No. 6,306,820 or the specification on page 16, line 5 and page 17, lines 4-5.

This rejection is traversed on the grounds that U.S. Patent No. 6,037,454 is not available as prior art under 35 U.S.C. §103(a) as §103(c) applies. Both patent '454 (see cover page) and the present application (recorded on reel/frame 011737/0739) were assigned to Genentech, Inc. and were commonly owned at the time the claimed invention was made. Patent '820 fails to teach or suggest any anti-LFA-1 antagonist let alone anti-CD11a antibody in combination therapy with a TNF-α antagonist in a method of treating RA. The known description of ENBREL alone does not render accomplish the method of the claimed invention. Therefore, the claims cannot be obvious.

Applicants request that this §103 rejection be withdrawn.

CONCLUSION

Applicants submit that the above discussion is fully responsive to all grounds of rejection set forth in the Office Action. In view of the comments above, Applicants respectfully request that all outstanding rejections be withdrawn, and that the pending claims, as amended, be allowed. The issuance of a formal Notice of Allowance at an early date is respectfully requested.

If a telephone interview would be of assistance in advancing prosecution of this application, the Examiner is invited to telephone the undersigned at the number provided below.

In the unlikely event that the transmittal letter is separated from this document and the Patent Office determines that an extension and/or other relief is required, applicant petitions for any required relief including extensions of time and authorizes the Commissioner to charge the cost of such petitions and/or other fees due in connection with the filing of this document to Deposit Account No. 07-0630 (Ref. Docket No. P1795R1). However, the Commissioner is not authorized to charge the cost of the issue fee to the Deposit Account.

Respectfully submitted,
GENENTECH, INC.

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